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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/718,278	HOSSAINY ET AL.	
	Examiner	Art Unit	
	Charlesworth Rae	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *14-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 10/3/07, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

This action is made final.

Status of the Claims

Claims1-26 are currently pending in this application.

Claims 14-26 are withdrawn.

Claims 1-13 are presented for examination.

Terminal Disclaimers

Terminal Disclaimers received 10/3/07 with respect to US Patent 7,169,404, and copending application 11/641,250, are acknowledged. It is noted that approval of the terminal disclaimers is still pending.

Response to applicant's arguments/remarks

Rejection under 112, 2nd para.

Applicant contends that this rejection is rendered moot in view of the amendments to claims 3 and 6.

In response, this rejection is withdrawn in view of the amendment.

Lack of written description rejection under 112, first para.

Applicant contends that this rejection is rendered moot in view of the amendments of claims 3, 9, and 13.

In response, this rejection is maintained for the reasons set forth below:

i) Claim 13 recites recite the terms "peptides, antisense agents, ... and diazenium diolates" which only correspond in some undefined way to the specifically disclosed chemicals. None of the undisclosed "peptides, antisense agents, ... and diazenium diolates" chemicals meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. To the extent that claim 13 depends from claim 12, which depends from claim 1, claims 1-13 are found to encompass undisclosed "peptides, antisense agents, ... and diazenium diolates" biologically active compounds.

Rejection under 102(b)

Applicant contends that this rejection should be withdrawn for the following reasons:

i) Llanos et al. describes a medical device comprising a coating that includes a copolymer formed by a first moiety selected from vinylidene fluoride (VDF) or tetrafluoroethylenw (TFE) and a second moiety that provides toughness or elastomeric properties to the copolymer, but do not teach a coating having a) a fluorinated polymer and b) a biologically beneficial polymer as defined in claim 1.

ii) Unlike the cited prior art, applicant asserts that claim 1 defines a medical article comprising a coating disposed on at least a portion of an implantable device, wherein the coating comprises a) a fluorinated polymer; and (b) a biologically beneficial polymer, and further wherein the biologically beneficial polymer is selected from poly(ethylene glycol)(PEG), block-copolymers of PEG with poly(butyleneterephthalate)(PBT), hyaluronic acid, poly(ethylene oxide-co-propylene oxide), phosphoryl choline, poylaspirin, or poly(ester amide) polymers.

In response, the rejection is maintained as applicant arguments are not found to be persuasive for the reasons previously made of record in the Office action mailed 7/25/07 at pages 6-8) and for the additional reasons set forth below:

i) Applicant's above arguments are directed to limitations that are not recited in the instant claims.

ii) It is the examiner's position that the instant claims do not preclude a medical device comprising a coating that includes a copolymer formed by a first moiety selected from vinylidene fluoride (VDF) or tetrafluoroethylene (TFE) and a second moiety that provides toughness or elastomeric properties to the copolymer as taught by Llanos et al. (para 0010 to para 0015, and Example 5).

Rejection under 103(a)

Applicant contends that this rejection should be withdrawn as the cited prior art references fail to teach or suggest all of the instant claimed limitations for the following reasons:

1) Kashiwagi et al. (US Patent 6,756,458) fails to describe or teach a biologically beneficial polymer as defined by claim 1.

2) Llanos fails to describe or teach the biologically beneficial polymer as defined by claim 1.

In response, the rejection is maintained for the reasons previously made of record in the Office action mailed 7/25/07 at pages 8-10 and for the additional reasons set forth below:

i) Applicant's above arguments are directed to limitations that are not recited in the instant claims.

ii) It is the examiner's position that the instant claims do not preclude a medical device comprising a coating that includes a copolymer formed by a first moiety selected from vinylidene fluoride (VDF) or tetrafluoroethylene (TFE) and a second moiety that provides toughness or elastomeric properties to the copolymer as taught by Llanos et al. (para 0010 to para 0015, and Example 5).

iii) Based on the teaching of the advantages of fluorinated diene polymers, someone of skill in the art would have been motivated to combine the teaching of Lllanos and Kashiwagi et al. to created the instant claimed invention.

Obviousness-type double patenting (ODP) rejections

Applicant contends that the rejections should be withdrawn for the following reasons:

1) ODP rejection based on US Patent 7,169,404 is rendered moot by the filing of the terminal disclaimer.

2) Provisional ODP rejection based on co-pending application 11/641,250 is rendered moot by the filing of the terminal disclaimer.

In response, the rejections are maintained as the terminal disclaimers have not yet been approved.

Objections to the Claims

Claim 1 is objected to for using improper Markush claim language. Specifically, claim 1 recites the *language "wherein the biologically beneficial polymer is selected from poly(ethylene glycol) ..., or poly ester amide polymers."*

Correction of this deficiency is requested.

REJECTIONS

Claim rejections – 35 USC 112 – Second Paragraph

The following is a quotation of the second paragraph of 35 USC 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the confusing term *"wherein the biologically beneficial polymer is selected from poly(ethylene glycol)(PEG). PEG, block-copolymers of PEG with poly(butyleneterephthalate) (PBT), hyaluronic acid, phosphoryl choline, poly(ethglene oxide-co-propylene oxide), polyaspirin, or poly(ester amide) polymers."* The recitation of

the period punctuation mark after the parenthesis in the term *"poly(ethylene glycol)(PEG)."* renders the claim unclear. In addition, the term *"(PEG). (PEG), block-copolymers ..."* is renders the claimed subject matter indefinite as it is not clear if the term "(PEG)" following the period is redundant or further qualifies the term "block-copolymers. Also, the recitation of the term , *"block-copolymers of PEG with poly(butyleneterephthalate) (PBT)"* renders the claimed subject matter indefinite because it is unclear whether the term "(PBT)" specifically refers to "*poly (butyleneterephthalate)" or "block-copolymers of PEG with poly(butyleneterephthalate)" or is a separate term.*

Dependent claims 2-13 are rejected for the same reasons as these claims fail to correct the deficiency of the claim from which they depend.

Claim 13 recites the terms " EVEROLIMUS," but fails to state the full meaning of the term at the first occurrence the term is recited in the claim. This limitation is vague and indefinite because it is not clear what " EVEROLIMUS" means. It is suggested that this specific rejection may be overcome by either replacing the terms with the full generic name or, alternatively, amend the claim by inserting the full name in parenthesis at the first occurrence of the term in the claim set. It is also noted that even though the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim rejections – 112 – First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

LACK OF WRITTEN DESCRIPTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

Claims 1-13 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The above discussion in connection with the Response to applicant's arguments/remarks with respect to the lack of written description under 112, 1st paragraph, is incorporated by reference.

The specification discloses specific biologically active agents, including rapamycin, which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claims 1-13 encompass undisclosed biologically active agents, including peptides, and antisense agents which only correspond in some undefined way to the specifically disclosed chemicals. In particular claim 12 recites the term *"a biologically active agent,"* while claim 13 recites the terms *"peptides, antisense agents."* None of undisclosed biologically active agents meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought,

he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed derivatives, analogs, biologically agent(s) etc., regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmacentical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the specifically disclosed chemically structurally defined chemicals, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

Claim rejections – 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4, 8-13 are rejected under 35 USC 102(b) as being anticipated by Llanos et al. (US Patent Publication No. 2002/0094440 A1).

Llanos et al. teach biocompatible coatings and films for use on *implantable medical devices* (page 1, para.0010, lines 1-5); the instant invention is directed to medical article, which is reasonably construed to be the same as a device. Llanos et al. teach coatings comprising a film-forming polyfluoro copolymer comprising the polymerized residue of a first moiety selected from the group consisting of vinylidenefluoride (VDF) and tetrefluoroethylerne (TFE), and the polymerized residue of a second moiety other than said first moiety and which is copolymerized with said first moiety; the second moiety being capable of providing toughness or elastomeric properties to the polyfluoro copolymer (page 1, para. 0010, lines 7-20). The first polymer moiety (TFE) of the *coating* taught by Llanos et al. is a *fluorinated polymer*; limitation "a" as recited in instant claim 1 is a fluorinated polymer. The second polymer moiety of the coating as taught by Llanos et al. is reasonably construed to be a *beneficial polymer* (=

limitation "b" as recited in instant claim 1); see applicant's disclosure for the definition of "biologically beneficial" (US Patent Application Publication No. 2005/0106204 A1, page 1, para. 0015; and page 6, Example 4). Llanos et al. teach stents coated with said polymeric coatings (page 1, para. 0015, lines 1-3); instant claim 2 recites the limitation "*stent.*" Llanos et al. teach Solef (page 5, Example 1). As stated above, instant claims 4, 7, 8, 9, 10, and 11 read on Solef. Solef is reasonably construed to be a biologically beneficial polymer (and a fluorinated polymer) because it is present in a medical product/device that would bring about biological benefits to a patient ... (see instant specification, page 1, para. 0015]. It is noted that there is no requirement in the instant claims that the " a fluorinated polymer" and the "a biologically beneficial polymer" be different polymers i.e. a single fluorinated polymer may reasonably satisfy the requirements of a biologically beneficial polymer and a fluorinated polymer. Llanos et al. exemplifies a coating comprising poly (VDF/HFP) and rapamycin (page 5, Example 3). Rapamycin is a biologically active agent in view of instant claim 13. The term "adduct" as recited in claim 12, when given its broadest reasonable possible interpretation is reasonably construed to mean to bring together (Webster's Collegiate Dictionary (1981, page 14). To the extent that the poly (VDF/HFP) is a fluorinated polymer and also reasonably serve as a biologically beneficial polymer, the coating comprising poly (VDF/HFP) and rapamyicin of Example 3 as taught by Llanos et al., is construed to satisfy the term *"wherein the biologically beneficial polymer is a polymeric adduct comprising a biologically active agent,"* as recited in instant claim 12. It

necessarily follows that the limitations of instant claim 13 would also be satisfied because it discloses rapamycin as a biologically active agent.

Claim rejections – 35 USC 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 3, 5-6 are rejected as being unpatentable over Llanos et al. (US Patent Application Publication No. 2002/0094440 A1; **already made of record by applicant as reference A123, received 9/9/05**) and Kashiwagi et al. (US Patent 6,756,458 B2).

The discussion of Llanos et al. in connection with the above rejection under 102(b) is incorporated by reference. Llanos et al. do not teach copolymers of perfluoro-

2,2-dimethyl-1,3-dioxole with perfluoroolefins or with perfluoro(alkyl viunyl) ethers, or cyclic esters of poly(perhalo-2,2-dimethyl-1,3-dioxole-xo-perfluoro-2-methylene-methyl-1,3-diolane.

Kashiwagi et al. (US Patent 6,756,458 B2) teach a method of producing fluorinated diene polymers via cyclopolymerization, and copolymerization of different polmers (col. 1, line 37 to col. 2, line 64; col 6, lines 16-37). Kashiwagii et al. teach copolymerizable other monomers are not particularly limited so long as they are radical polymerizable monomers, and a wide range of fluoromonomers, hydrocarbon monomers and other monomers, may be mentioned e.g. olefin such as ethylene, or a fluoroolefin such as tetrafluoroethylene are particularly preferred (col. 6, lines 38-41). A fluorinated vinyl ether type monomer such as a perfluoro(alkyl vinyl ether), a cyclopolymerizable fluorinated diene (other than the fluorinated diene represented by the formula 1) such as perfluoro(butenyl vinyl ether) or perfluoro(allyl vinyl ether) or a monomer having a fluorinated alicyclic structure such as perfluoro(2,2-dimethyl-1,3-dioxole), may, for example, be also copolymerizable; such other monomers may be copolymerized with the fluorinated diene, alone or in combination of two or more of

them (col. 6, lines 43-52). Instant claim 3 recite the term " *copolymers of perfluoro-2,2-dimethyl-1,3-dioxole with perfluoroolefins or with perfluoro(alkyl vinyl ether."* Instant claim 5 recites the term " cyclic esters of poly(perhalo-2,2-dimethyl-1,3-dioxole-xo-perfluoro-2-methylene-methyl-1,3-diolane." Instant claim 6 recites " perfluorallyl vinyl ether and/or perfluorobutenyl.

Based on the teaching of Kashiwagit et al. that the fluorinated diene polymers maintain their mechanical properties at high temperatures, someone of skill in the art would have been motivated to combine the teaching of Lllanos et al., in view of Kashiwagi et al. to create the instant claimed invention for use in patients, for example, with a high temperature (i.e. fever).

Thus, someone of skill in the art at the time the instant invention was made would have deemed it obvious to create the instant claimed invention with a reasonable expectation of success.

Nonstatutory Obviousness-Type Double-Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent 7,169,404, in view of Llanos et al. (US Patent Publication No. 2002/0094440 A1) and Kashiwagit et al. (US Patent 6,756,458 B2). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are either anticipated by, or would have been obvious in view of the referenced claims.

Reference claim 1, an medical article comprising an implantable substrate having a coating, the coating including an ABA or an AB block copolymer, the block copolymer having A and B blocks and an **active agent conjugated to the block copolymer**, wherein one of the blocks comprises a biological moiety and the other block comprises a structural moiety that provides the block copolymer with structural functionality, wherein the structural moiety comprises poly(butylene terephthalate), poly(ester amide), poly(lactic acid), or copolymers thereof, and wherein the active agent conjugated to the block copolymer is diazenium diolate. While reference claim 5, for example, recites the limitation "wherein the biological moiety is selected from a group consisting of poly(alkylene glycols), poly(ethylene oxide), poly(ethylene oxide-co-propylene oxide), poly(N-vinyl pyrrolidone), poly(acrylamide methyl propane sulfonic acid) and salts thereof, sulfonated dextran, polyphosphazenes, poly(orthoesters), poly(tyrosine carbonate), hyaluronic acid, hyaluronic acid having a stearoyl or palmitoyl substitutent group, poly(ethylene glycol)-hyaluronic acid, poly(ethylene glycol)-hyaluronic acid-stearoyl, poly(ethylene glycol)-hyaluronic acid-palmitoyl, heparin, poly(ethylene glycol)-heparin, and copolymers thereof. Reference claim 7 recites the limitation "wherein the block copolymer is selected from a group consisting of poly(ethylene-glycol)-block-poly(butyleneterephthalate)-block-poly(ethylene-glycol), poly(butyleneterephthalate)-block-poly(ethylene-glycol)-block poly(butyleneterephthalate), poly(ethylene-glycol)-block-poly(butyleneterephthalate), poly(ethylene-glycol)-block-poly(lactic acid)-block-poly(ethylene-glycol), poly(lactic acid)-block-poly(ethylene-glycol)-block-poly(lactic acid)

and blends thereof. Unlike the instant claims, the reference claims do not recite the term "fluoropolymers."

The below discussion of Llanos et al. (US Patent Publication No. 2002/0094440 A1) in connection with the 102(b) rejection, and the above discussion of Kashiwagi et al. in connection with the 103(a) rejection, are incorporated by reference. Someone of skill in the art would have deemed it obvious to incorporate a fluorinated copolymer as part of the ABA or BA block copolymer to create the instant inventive concept.

Thus, someone of skill in the art at the time the instant invention was made would have deemed it obvious to create the instant invention with a reasonable expectation of success in view.

Claims 1-13 are rejected on the ground of nonstatutory obviousness-type double patenting (ODP) as being unpatentable over claims 1-11, and 20-21 of copending U.S. Patent Application No. 11/641,250 (also, US Patent Application Publication No. 20070098758), in view of Llanos et al. (US Patent Publication No. 2002/0094440 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are either anticipated by, or would have been obvious in view of the referenced claims.

In particular, reference claim 1 is directed to an implantable substrate having a coating, wherein the coating comprise an ABNA or an AB block polymer, the block polymer having A and B blocks, wherein one of the blocks comprises a biological moiety that produces a biological copolymer with structural functionality, and wherein the structural moiety comprises poly(butylenes terephthalate, poly(ester amide),

poly(lactic acid), or copolymers thereof. Someone of skill in the art would have deemed it obvious to create the instant claimed invention with reasonable predictability.

Thus, someone of skill in the art at the time the instant invention was made would have deemed it obvious to create the instant invention with a reasonable expectation of success for the same reasons as stated above (with respect to ODP rejection in connection with US Patent 7,169,404).

This is a provisional obviousness-type double patenting rejection because the conflicting claims of the copending applications have not in fact been patented.

Relevant Prior Art

The following post-dated art are made of record and relied as being pertinent to applicant's invention.

Branca (US Patent 5,708,044) teach a blend of resin composition of polytetrafluoroethylene (PTFE) porous material having a microstructure of nodes interconnected by fibrils, wherein the said material comprises a blend of two different polytetrafluoroethylenes, one polytetrafluoroethylene being a homopolymer of tetrafluoroethylene and the other polytetrafluoroethylene being a modified polymer of tetrafluoroethylene (col. 1, line 61 to col. 2, line 10). The blending technique is optimized to provide a desired balance node size and fibril length with addtional property of thermal stability in the resullting stretched material (col. 1, lines 14-25, and lines 61-65). Branca teach that the preferred modified homopolymer commonomer units are supplied by fluorinated ethylenically unsaturated comonomers e.g.

hexafluoropropylene or perfluoro(alkyl ether), usually perfluoro(propyl vinyl ether (col 3, lines 14-43).

Fuller (US Patent 6,416,834) teach an adhesion-promoting additive composition for use in elastomers which are desirable for use in a wide variety of commerical products, including wire coatings (col. 1, lines 11-19). In one embodiment, the invention is directed to a composition for improving adhesion between an elastomer and a fluoropolymer comprising A) a first polymer comprising an uncured unsaturated polymeric adduct formed by reacting a polymer having unsaturation in the backbone of the polymer chain with an unsaturated dicarboxylic acid or dicarboxylic acid anhydride, wherein the acid or anhydride moieties comprise at least three weight percent of the adduct, and B) a compound selected the group consisting of polyamino primary amines, polyamino primary amine carbamates, and condensation products of polyamino primary amines with aldehydes(col. 1, lines 44-55). Fuller disclose non-eleastomeric fluoropolymer layer composed of non-elastomeric tetrafluoroethylene polymers, including, polytetrafluoroethylene, coplymers of tetrafluoroethylene and fluorohexapropylene, copolymers of tetrafluoroethylene and perfluror(alkyl vinly) ether and copolymers of tetrafluoroethylene and ethylene; polyvinylidene fluoride or copolymers of vinylidene fluoride with at least one monomer selected from the group consisting of fluorohexapropylene and tetrafluoroethylene may be utilized (col. 5, line 48 to col. 6, line 52).

Castro et al. (6,953,560) teach a method for local delivery of drug involving **coating a stent or graft with a polymeric material** which, in turn, is impregnated with

a drug or a combination of drugs; once the stent or graft is **implanted within a cardiovascular system lumen**, the drug(s) is released from the polymer for the treatment of the local tissue (col. 1, line 46 to col. 2, line 13). The implantable device includes a substrate e.g. a metal or polymeric stent or graft (col. 3, lines 27-30). At least a portion of the substrate is coated with a first layer that includes one or more drugs in a **polymeric carrier**; **a barrier coating** overlies the first layer (which reduces the rate of release of the drug from the polymer once the medical device is placed into a patient's body (col. 3, lines 30-37). Castro et al. teach that some organic compounds e.g. polyacrylonitrile, polyvinylidene chloride, nylon- 6-6, perfluoropolymers, polyethylene terephthalate, polyethylene 2,6-napthalene dicarboxylate, and polycarbonate may be incorporated in the biocompatible barrier (col. 3, line 38-46; col. 6, line 52 to col. 7, 21) Instant claim 1 is directed to an implantable medical device (i.e. reference teaches a stent or graft), a coating comprising a fluorinated polymer (reference teaches a polymeric carrier and a barrier coating for delivery of a drug; the first polymeric layer can include e.g. fluoropolymers, ethylene vinly acetate, poly(n-butyl methacrylate), ethylene vinyl alcohol copolymer, polymethylmethacrylate, and mixtures thereof. Castro et al. teach rapamycin in polymethyl-methacrylate or poly (n-butyl) methacrylate (col. 7, line 18-19).

Fukushi (US Patent 6,759,129) teach multi-layer article comprising a first polymer layer, a substrate, and a bonding layer on a surface of the first polymer layer which is in conact with the substrate, wherein the first polymer layer includes a fluoropolymer; the bonding layer includes a fluroelastomer comprising a monomer

segment derived from an olefinic hydrocarbon (col, 1, lines 56-62). The fluoroelastomer can be a copolymer, which in addition to the olefinic hydrocarbon monomer, can be derived from fluorinated monomers e.g. Tetrafluoroethylene, vinylidene fluoride, hexafluoropropylene, fluorinated vinyl ethers or combination thereof (col. 2, lines 4-12; col. 6, lines 16-36). The substrate may include an inorganic substrate, such as a metal or an inorganic glass, or an organic substrate, such as a fluoropolymer or a non-fluorinated polymer (e.g. a polyamide, a polyolefin, a polyurethane, a polyester, a polyimide, a polystyrene, a polycarbonate, a polyketone, a polyurea, a polyacryklate, and a polymethyl methacrykate, or a mixture thereof) (col. 6, line 56 to col 7, line 33). Useful polyols include, polypentyleneadipate, glycol, polytetramethylene ether glycol, polyethylene glycol, polycaprolactone diol, poly-1,2-butylene oxide glycol, and combinations thereof (col. 7, lines 46-49). Instant claim 7 recites the term poly(ethylene) glycol.

Davila et al. (US Patent 7,056,550) teach a medical device for implantation into a treatment site of a living organism comprising a biocompatible vehicle affixed to at least a portion of the medical device, and at least one agent in therapeutic dosages incorporated into the biocompatible vehicle (col. 5, lines 24-53). Davila et al. exemplify a polyfluroro copolymer (Solef 21508) coating. In one aspect of the invention, the implantable medical device comprises a stent (col. 5, line 54 to col. 6, line 19). Davila et

al. teach a method of coating the implantable medical device comprising the steps of creating a polymer utilizing vinylidene fluoride and hexafluoropropylene in a batch emulsion polymerization process (col. 6, lines 20-31). Davila et al. teach that rapamycin may be incorporated onto or affixed to the stent e.g. rapamycin may be directly incorporated into a polymeric matrix and sprayed onto the outer surface of the stent (col. 13, lines 39-47); any number of non-erodible polymers may be sued in conjunction with rapamycin e.g. a solution of poly(ethylene-co-vinylacetate) and polybutylmerthacrylate may comprise the base layer of a bilayered polymeric matrix (col. 13, lines 48-67). Davila et al teach polymeric coating comprising a polyfluoro copolymer, without limitation, e.g. hexafluoropropylene (HFP), tetrafluoroethylene (TFE), vinlyidenefluoride, 1-hydropentafluoropropylene, perfluoro(methyl vinyl ether), chlorotrifluoroethylene (CTFE), pentafluoropropene, trifluoroethylene, hexafluoroacetone and hexafluroisobutylene (col. 15, lines 32-44). Davila et al. teach that suitable nonmetallic biocompatible materials for use with stents, include, but not limited to, polyamides, polyolefins (i.e. polypropylene, polyethylene), nonabsrobable

polyesters (i.e. polyethylene terephthalate), and bioabsrobable aliphatic polyesters (i.e. homopolymers and copolymers of lactic acid, glycolic acid, lactide glycolide, para-dioxanone, trimethylene carbonated, ε-caprolactone, and blends thereof (col. 17, lines 4-17).

Nakamura et al. (US patent 4,910,276) teach a cyclic polymerization method for producing fluorine-containing polymers (col. 1, line 4 to col. 8, line 20).

(8) Cohn (EP 0396429; already made of record by applicant) teach polyurethane-based polymeric materials and biomedical articles and pharmaceutical compositions comprising said polyurethane-based polymers, including block polyurethane amides (PEUAm) containing halogen substitutents (see abstract)

In looking at the continuity data, it is noted that applicant has numerous issued patent and pending applications encompassing the same or similar subject matter of the instant application. Applicant should review all subject matter considered the same or similar, and submit the appropriate Terminal Disclaimer(s). For example, the following US Patents may encompass the same or similar subject matter(s): 6,908,624; 7,186,789; and 7,214,759.

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THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http:pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

6 December 2007
CER

BRIAN-YONG S. KWON
PRIMARY EXAMINER